IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	YAMAOKA ET AL.	Examiner:	M. MEAH
Serial No.:	10/526026	Group Art Unit:	1652
Filed:	February 28, 2005	Docket No.:	10921.0286USWO
Title:	METHOD FOR PURIFYING PROTEIN AND GLUCOSE DEHYDROGENASE		

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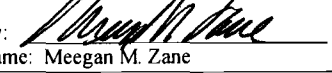
By: 
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APPELLANTS' REPLY BRIEF TO EXAMINER'S ANSWER UNDER 37 C.F.R. §41.41

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief is submitted in the above-referenced application, in response to the Examiner's Answer mailed July 23, 2010, and in accordance with 37 C.F.R. §41.41. This Reply Brief is presented in further support of the Notice of Appeal filed February 1, 2010 and Appellants' Brief on Appeal filed March 31, 2010.

At pages 8-9, the Examiner's Answer alleges that there is a finite number of predictable alternatives, that claim 1 is obvious as it would be a simple replacement of the ion exchange resin used by Sode with the ion exchange resin available in the Amersham Catalog and a replacement of the elution buffer of Sode with a cholate buffer in Shimomura et al., and that one of skill in the art would have therefore been motivated to combine the references cited. Appellants contend that this conclusion is unsupported by the present record.

While Shimomura et al. uses cholate in its buffers, such buffers are aimed at serial purification of a specific protein Complex III, which is a completely different protein from the target protein of claim 1, i.e. glucose dehydrogenase derived from a microorganism belonging to the genus Burkholderia and has α, β, γ subunits. Appellants' claim 1 is a method that employs a column with a specific type of ion exchange resin and a specific type of eluent, so as to achieve purification of the glucose dehydrogenase. Claim 1 provides a method for isolation of a protein that has both electron transfer capability and glucose dehydrogenation activity. See e.g. page 3, lines 22-26 of Appellants' specification. Furthermore, Shimomura et al. employs buffer profiles that are directed to serially isolating certain specific subunits of its protein Complex III. However, there is nothing in the present record to suggest the buffers of Sode simply could be replaced with the buffers taught in Shimomura et al., given the specificity of the isolation models and buffer profiles used to obtain certain subunits of the Complex III. Moreover, there is no reason that one of skill in the art would expect that such cholate buffers would be useful to purify a completely different protein, the glucose dehydrogenase of claim 1, so as to provide a protein with both electron transfer capability and glucose dehydrogenation activity.

Moreover, it is understood that amino acid sequences of a protein determine its structural and functional properties and, as such, purification techniques are specific for obtaining useful results with desired activity and utility. This was specifically acknowledged, and in fact heavily relied upon by the Examiner in the Office Action mailed June 13, 2006 (see e.g. pages 7-8). Indeed, Shimomura et al. employs specific buffer profiles directed to serially isolating certain specific subunits of a different protein

Complex III. Given the specificity required to isolate a protein, there is no reason for one of skill in the art to predict the replacement of the sodium chloride buffer of Sode with any of the buffers of Shimomura et al., without the benefit of Appellants' disclosure. The Examiner's position here is inconsistent with his previous holdings about the unpredictable art of protein chemistry.

For the foregoing reasons, Appellants respectfully contend that a prima facie obviousness has not been shown, as a suggestion or motivation to combine or modify the references has not been shown. Claim 1 and its dependents are patentable over the references cited. Reversal of the rejection is respectfully requested.

At page 10 of the Examiner's Answer, the conclusion is made that there is nothing surprising or unexpected in Appellants' method claim 1 and that the unexpected results are not relevant since the claims do not specify any particular level of purity.

Appellants respectfully contend that such a conclusion is incorrect. As the prior art does not teach, suggest, or predict the method of claim 1, there is no reason to expect that one of skill in the art would arrive at claim 1 or realize its benefits. Furthermore, as reported above in Examples 1-4 compared to Comparative Examples 1-2, the method as recited in claim 1 can provide higher specific activities of the protein over other purification methods, such as those using a sodium chloride buffer. There is no need for the claim to recite all of the advantages that the claimed invention provides, such as a level of purity.

For the foregoing reasons, Appellants respectfully contend that a reasonable expectation has not been shown in the references cited that would lead one of skill in the

art to Appellants' claimed invention. Claims 1, 7, and the remaining dependents are patentable over the references cited. Reversal of the rejection is respectfully requested.

Appellants submit that the rejection is untenable for the reasons set forth above and should be reversed. Please charge any additional fees or credit any overpayment to Deposit Account No. 50-3478.

Respectfully submitted,

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Date: September 23, 2010

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